PREMARKET NOTIFICATION [510(k)] Summary

This Summary of Safety and Effectiveness is prepared in accordance with 21 CFR Part 807.92(c).

1. **Company Name:**
Chison Medical Imaging Co., Ltd.
No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142
Chison Medical Imaging Co., Ltd.
No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

Contact: Ms. Ruoli Mo
Tel: +86-510-85311707, 85310593 Fax: +86-510-85310726

U.S. Agent:
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
Dublin, CA 94568

Contact: Bob Leiker
Tel: (925) 556-1302 Fax: (866) 718-3819

2. **Device Name:** CHISON iVis 20 & iVis 30 & i3 (Rollaround)
& Q1&Q2&Q3&Q5Roll (Portable) Diagnostic Ultrasound System

Common/Usual Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

2. **Marketed Device:**
K101236, GE Voluson E6/E8 /E8 Expert Diagnostic Ultrasound System

3. **Device Description:**
The CHISON iVis20/iVis30/i3/ Q1/Q2/Q3/Q5 ultrasound system is an integrated preprogrammed color doppler ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The CHISON ultrasound system can be configured as a roll-around model on wheels (iVis20/iVis30/i3/ Q1/Q2/Q3/Q5). These systems are designed with the latest technology, using the same quality procedure as ultrasound systems which have been available in the market for years.

This CHISON ultrasound system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound echo data and display the image in B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, or a combination of these modes.

The CHISON iVis Models and Q Models and i3, have been designed to meet the following product safety standards: NEMA UD 2, NEMA UD 3, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC 10993-1.

4. **Indications for Use:**
   The system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.), Peripheral Vascular, Transvaginal, Transrectal, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, OB/Gyn and Urology.

5. **Comparison to Predicate Device:**
   The CHISON iVis Models and Q Models and i3 are of comparable type and substantially equivalent to the current Voluson E8 (K101236). All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have the same intended uses and basic operating modes as the predicate device. All systems allow for specialized measurements of structures and flow, and calculations.

6. **Conclusion:**
   The CHISON iVis Models and Q Models and i3 are substantially equivalent in safety and effectiveness to the predicate systems. The systems are intended for diagnostic ultrasound imaging and fluid flow analysis. The systems have the same gray-scale and Doppler capabilities. The systems have acoustic output levels below the applicable FDA limits. The systems are designed to applicable electrical and physical safety standards.

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB - 3 2012

Chison Medical Imaging Co., Ltd.
% Mr. Bob Leiker
Owner, U.S. Agent
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
DUBLIN CA 94568

Re: K113359
Trade/Device Name: CHISON iVis Series & Q Series, i3 Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: November 4, 2011
Received: November 14, 2011

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CHISON iVis Series & Q Series, i3 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

D3C60L, 2.5-4.0MHz Convex Array
D4C40L, 3.0-6.4MHz Convex Array
D6C12L, 5.3-10MHz Micro-convex Array
D7C10L, 5.33-10MHz Micro-convex Array
D7L40L, 5.3-10MHz Linear Array

D7L60L, 5.33-10MHz Linear Array
V4C40L, 3.0-5.3 MHz Convex Array
D6C15L, 4.0-8.0MHz Convex Array
D7L30L, 5.33-10MHz Linear Array
D5C20L, 4.0-8.0MHz Convex Array
D3C20L, 2.5-4.0MHz convex Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use

1.3 Indications for Use

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.), Peripheral Vascular, Transvaginal, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, OB/Gyn and Urology.

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113359

Prescription Use √ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications For Use

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N							N
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal	N	N	N		N	N	Note 1	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	
	Cardiac Pediatric	N	N	N		N	N	Note 1	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Other*: 3-D , 4-D Imaging, [1] Small Organ: Thyroid, parathyroid, parotid,submaxillary gland, testes and breast

Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113359

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D3C60L, 2.5-4.0MHz Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113359

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D4C40L,3.0-6.4MHz Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113359

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D6C12L, 5.3-10MHz Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans- rectal								
	Trans- vaginal	N	N	N		N	N	Note 1	
	Trans- urethral								
	Trans- esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D7C10L, 5.33-10MHz Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans- rectal								
	Trans- vaginal	N	N	N		N	N	Note 1	
	Trans-urethral								
	Trans- esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113359

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D7L40L, 5.3-10MHz Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans- rectal								
	Trans- vaginal								
	Trans-urethral								
	Trans- esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	
	Intravascular								
	Other(Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Additional Comments: [1] Small Organ: Thyroid, parathyroid, parotid,submaxillary gland, testes and breast
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Section 1.3 510K K113359 Indications For Use

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D7L60L, 5.33-10MHz Linear Array

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans- rectal								
	Trans- vaginal								
	Trans-urethral								
	Trans- esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	
	Intravascular								
	Other(Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	
	Other (Specify)								

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Additional Comments: [1] Thyroid, parathyroid, parotid,submaxillary gland, testes and breast
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: V4C40L, 3.0-5.3 MHz Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N							N
	Abdominal	N	N	N		N	N	N	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	N	
	Other (Ob/GYN)	N	N	N		N	N	N	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Other*: 3-D , 4-D Imaging
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D6C15L, 4.0-8.0MHz Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113359

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D7L30L, 5.33-10MHz Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	
	Intravascular								
	Other(Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Note 3: CWD Mode is not available on all transducers.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113359

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D5C20L, 4.0-8.0MHz convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	
	Cardiac Pediatric	N	N	N		N	N	Note 1	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Note 3: CWD Mode is not available on all transducers.

Additional Comments:

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113339

System: CHISON iVis Series & Q Series ,i3 Diagnostic Ultrasound Systems
Transducer: D3C20L, 2.5-4.0MHz convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	
	Cardiac Pediatric	N	N	N		N	N	Note 1	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Note 3: CWD Mode is not available on all transducers.

Additional Comments:

Prescription Use √ AND/OR Over-The-Counter Use

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